

REMARKS

Claims 27, 30, 31, 60, 74, 79-82, and 86 are pending, and were allowed by the Examiner in the Office Action mailed February 23, 2005. Claims 61, 64-73, and 83 are cancelled by the present amendment. No new matter has been added.

Interview Summary

Applicants would like to thank the Examiner for her courtesy in speaking with the undersigned and Louis Myers by telephone on March 9th and 11th, 2005, in regards to the pending enablement rejection under 35 U.S.C. § 112 ¶1. Applicants regret that no agreement on claims 61, 64-73 and 83 was reached during that conversation.

Claim Rejections under 35 U.S.C. § 112

While Applicants do not share the Examiner's views regarding the non-enablement of claims 61, 64-73 and 83, Applicants have cancelled those claims in the interest of furthering prosecution. Applicants wish to clarify that, in their view, the pending claims are enabled as written.

Claim 27, from which all pending claims in the application depend, reads as follows:

27. A method of producing and secreting insulin in a subject in vivo, the method comprising introducing into the subject an intermediate lobe pituitary cell that is capable of storing and secreting insulin and comprises a nucleic acid sequence encoding insulin, the nucleic acid sequence being operatively linked to a heterologous promoter that directs expression of the nucleic acid sequence in the intermediate lobe pituitary cell, thereby producing and secreting insulin in said subject.

It is Applicants' position that even if it is not enabled for some species (which Applicants do not concede), claim 27 covers any intermediate lobe pituitary cell that is capable of secreting insulin, regardless of whether that secretion is constitutive or glucose-sensitive. Applicants submit that, even if there are a significant number of inoperative embodiments (which, again, applicants do not concede), the pending claims are fully enabled. MPEP 2164.08(b) reads as follows:

The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be

inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984) (prophetic examples do not make the disclosure nonenabling).

Although, typically, inoperative embodiments are excluded by language in a claim (e.g., preamble), the scope of the claim may still not be enabled where undue experimentation is involved in determining those embodiments that are operable. A disclosure of a large number of operable embodiments and the identification of a single inoperative embodiment did not render a claim broader than the enabled scope because undue experimentation was not involved in determining those embodiments that were operable. *In re Angstadt*, 537 F.2d 498, 502-503, 190 USPQ 214, 218 (CCPA 1976). However, claims reading on significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984); *In re Cook*, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971). (emphasis added)

Thus the MPEP and *Atlas Powder* set forth a two-part test for non-enablement in the presence of possibly inoperative embodiments, both parts of which must be absent to render the claim non-enabled: first, does the specification clearly identify the operative embodiments? And second, is undue experimentation involved in determining those that are operative? Applicants submit that under this test, the pending claims are enabled.

1. The Specification Clearly Identifies the Operative Embodiments

Independent claim 27 is drawn to a method of producing insulin in a subject *in vivo*. This excludes any embodiment that does not produce insulin in a subject *in vivo*. The claim does not specify whether the production of insulin is regulated or non-regulated; it could be either; all that is specified is that the cells are capable of producing insulin. Thus, those embodiments that are inoperative, i.e., do not produce insulin, are clearly identified. (See MPEP 2164.08(b)). Claim 27 is drawn to the use of cells that are capable of producing insulin. That is what must be enabled. Applicants argue that species that secrete insulin in a glucose sensitive manner are also enabled, but even if they are not, the broader claim 27 is fully enabled. Even if the Examiner is correct, and species that secrete in a glucose-sensitive manner are not enabled, the enablement of

claim 27 is not affected; rather, one could, upon a showing of glucose-sensitive secretion of insulin, obtain an improvement patent (assuming all other requirements are met, of course).

2. No Undue Experimentation Is Involved in Determining which Embodiments Are Operative

The second question is whether one of skill in the art would be able to identify which embodiments are operative without undue experimentation, e.g., with no more experimentation than would be routine in the art. Applicants note that the Examples set forth in the specification include instructions for detecting the expression of insulin in mammals, see, e.g., Example 3, which describes the use of Northern blot analysis; and Example 4, which describes the use of metabolic labeling, immunoprecipitation and gel electrophoresis. One of skill in the art would readily be able to select an intermediate lobe pituitary cell, express insulin (and, optionally, other genes as well) in the cell, and test the cell to see if it produces insulin. Again, independent claim 27 does not specify whether the production of insulin is regulated or non-regulated; it could be either. Thus, no undue experimentation is required.

Applicants submit that both parts of the *Atlas Powder* test are met, and claim 27 is enabled. Following the holding of *Atlas Powder*, even if one of the two parts of the test were not met, the claims are still enabled.

Applicants note that it is clear that a claim can dominate yet-to-be-invented improvements. "It is apparent that such an inventor should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on his teachings. Such improvements, while unobvious from his teachings, are still within his contribution, since the improvement was made possible by his work." *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). Thus, even assuming *arguendo* that embodiments in which the "ideal" is achieved, i.e., perfect mimicry of a normal, functioning beta cell, are not presently enabled (which applicants do not concede) but are part of future refinements, the fact that the present claims could cover such embodiments does not render the present claims non-enabled. "A patent application cannot


enable technology that arises after the date of application. The law does not expect an applicant to disclose knowledge invented or developed after the filing date.” *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 2004 WL 61285 (Fed. Cir. 2004), citing *In re Hogan*, 559 F.2d 595, 605-06 (CCPA 1977). Therefore, even if it is later discovered that additional genes are necessary for reconstituting ideal glucose-sensitive secretion in these cells, lack of teaching regarding these genes does not make the present claim non-enabled – and such improvements would be within the scope of the pending claims.

Applicants wish to thank the Examiner for the previous allowance of claims 27, 30, 31, 60, 74, 79-82, and 86. Applicants respectfully request the issuance of a notice of allowance forthwith.

Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 10276-015002.

Respectfully submitted,

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Janice L. Kugler
Reg. No. 50,429

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906
21149928.doc